K100819

510(k) Summary

AUG 0 2 2010

6.1 Submitter Information

A.	Company Name:	Onset Medical, Inc.
B.	Company Address:	13900 Alton Parkway, Suite 120 Irvine, CA, 92618
C.	Company Phone:	(949) 716-1100
D.	Company Facsimile:	(949) 716-1101
E.	Contact Person:	Joseph Bishop Chief Executive Officer jbishop@onsetmedical.com

6.2 Device Identification

A.	Device Trade Name:	SoloPath™ Balloon Expandable TransFemoral Introducer
B.	Common Name:	Catheter Introducer
C.	Classification Name(s):	Introducer, Catheter
D.		Classification Regulation(s): 21 CFR 870.1340
E.	Device Class:	Class II
F.	Product Code:	DYB
G.	Advisory Panel:	Cardiovascular

6.3 Identification of Predicate Device

The predicate device is the SoloPath™ Balloon Expandable TransFemoral Introducer, that was cleared for commercial distribution under 510(k) K092014.

6.4 Device Description

The SoloPath™ Balloon Expandable TransFemoral Introducer is an intravascular catheter introducer and is Intended for travel over a 0.038" or smaller guidewire. The device includes a flexible Sheath composed of reinforced polymer that is compressed, folded and wrapped around a central, removable balloon dilatation catheter (the Expander). One radiopaque marker is located on the Sheath to indicate the end of the expandable portion of the Sheath.

The Expander balloon is non-compliant and size limited. The Expander has both an inflation lumen and a guidewire lumen. The Expander is configured to be used with standard inflation devices having an appropriate pressure rating, a male Luer lock coupler, and a capacity of 25-CC.

The Sheath is terminated, at its proximal end, by a hub having a straight through hemostasis port capable of accepting catheters equal to the full sheath inner diameter. An aspiration and infusion port, terminated with a 3-way stopcock, permits infusion of heparinized saline into the central port of the Sheath hub, prior to and during the procedure. The Expander incorporates a T connector, the through lumen port being terminated with a hemostasis valve for guidewire introduction, while the right angle port is for inflation of the Expander balloon. A separate aspiration and infusion side port, terminated with a 3-way stopcock, is also provided which permits fluid transfer into or from the guidewire lumen of the Expander.

6.5 Indications for Use

The SoloPath™ Balloon Expandable TransFemoral Introducer is intended to be inserted percutaneously into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters and /or devices introduced into the femoral iliac arteries.

6.6 Performance Testing

A program of design verification testing included ***in vitro*** bench testing that has been completed to demonstrate that the performance characteristics of the SoloPath™ Balloon Expandable TransFemoral Introducer are equivalent to the predicate device and satisfy the requirements of the product design specifications for its intended use.

The following tests were conducted to support the safety and effectiveness of the product.

1. Biocompatibility Testing per ISO 10993-1.
    a. Which includes Cytotoxicity, Complement Activation, PTT, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Pyrogen, and Hemolysis
2. Leakage testing including Hemostasis and Dilator Leakage Testing
3. Design/Functional Testing:
    a. Bend Testing
    b. Inflation/Deflation Testing
    c. Tensile Testing

6.7 Conclusions Drawn from Studies

The results of testing demonstrate that the SoloPath™ Balloon Expandable TransFemoral Introducer is substantially equivalent to the predicate device in design, function, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

AUG 0 2 2010

Onset Medical Corporation
c/o Mr. Joseph Bishop
Chief Executive Officer
13900 Alton Parkway, Suite 120
Irvine, CA 92618

Re: K100819
Trade/Device Name: SoloPath™ Balloon Expandable TransFemoral Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 29, 2010
Received: June 30, 2010

Dear Mr. Bishop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100819

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Device Name: SoloPath™ Balloon Expandable TransFemoral Introducer

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over the Counter Use_____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Nichols
(Division Sign-Off)
Division of Cardiovascular Devices

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